REMARKS

This application pertains to a novel abuse-proofed dosage form.

Claims 1, 2, 4, 7, 8, 27- 29 and 31 are pending; claim 6 being cancelled by this amendment. The limitations of cancelled claim 6 have been added to claim 1.

The claims have been amended to more specifically describe the dosage form as being a sintered mass. Support for this limitation can be found in the specification at page 24, lines 15-25, where the process of making the dosage form is described as **briefly** heating the tabletting tool to at least e.g. the sintering temperature of component (C) and cooled again; or heating the material to be pressed immediately prior to tabletting to at least the softening temperature of component (C) and then pressed. Further, Example 1 describes how a tabletting tool was heated to 80 Cº in a heating cabinet, and then the powder mixture was pressed with the heated tool. Example 2 describes how the **powder mixture** was heated to 80 Cº, and then pressed in a tabletting tool. Note that the powder mixture was heated to 80 Cº and then pressed, which clearly conveys to those skilled in the art that the mixture remained in powder form until pressed in the tabletting tool.

The term “sintering”, as used with respect to crystalline, granular or

powdered materials, as in the present case, means:

> The solidification of crystalline, granular or powdered ceramic materel by growing together of the crystallites when heated appropriately. During sintering however not all components should be melted. The growing together can take place by diffusion (solid/solid-reaction), in addition one of the components involved can melt, wet and coat the higher-melting components and will solidify when cooling down (fusion sintering).
> [see http://www.a-m.de/englisch/index.html].

and this is the meaning of the term "sintered" as used herein.

Those skilled in the art, noting the application of heat and pressure to the powder mixture to produce a product which has a hardness sufficient to withstand a force of 500 N without breaking, would clearly understand that the product had to have been sintered by the described process. Therefore, the amendment is supported by the specification.

Claims 1, 2, 4, 6-8, 27-29 and 31 stand rejected under 35 U.S.C. 112, second paragraph, because the Examiner finds it unclear as to what "quantities" of component (C) are required to provide a breaking strength of at least 500.

The claims have now been amended to specifically define the amount of component (C) to be that amount which is sufficient to result in the sintered mass having a breaking strength of at least 500 N. Those skilled in the art will be able to determine the amount required to do this, by testing their own particular formulations, with varying amounts of component (C), until the desired breaking

strength is obtained. This represents a very reasonable amount of experimentation, as would be expected by those skilled in the art, recognizing that the amount required may be affected by the nature and amounts of the specific additional components included in the specific formulation being considered, and may differ from one formulation to another. Such reasonable amount of experimentation is expected and well within the skills of the art, and therefore does not render the claim indefinite. The amount is definite, in that it is that amount sufficient to reach a breaking strength of at least 500 N.

The rejection of claims 1, 2, 4, 6-8, 27-29 and 31 under 35 U.S.C. 112, second paragraph should accordingly now be withdrawn.

Claims 1, 2, 4, 6-8, 27-29 and 31 stand rejected under 35 U.S.C. 103(a) as obvious over Oshlack et al. (US 2003/0064099A) in view of Zhang et al and Maggi et al.

The Examiner views Oshlack as disclosing a controlled release oral dosage form of an opioid analgesic having an aversive agent, such as polyethylene oxide. The Examiner points out that Oshlack's product can be in the form of a tablet, but nothing in Oshlack would teach or suggest how such tablets could be made to have a breaking strength of at least 500 N.

The Examiner turns to the Zhang reference for what she sees as a

disclosure of a product prepared by a hot-melt extrusion, and having PEO polymers in the molecular weight range of 1,000,000 and 7,000,000, which product can be formed into tablets. Still, however, there is no teaching or suggestion of how a breaking strength of at least 500 N. might be obtained, nor is there even a recognition of breaking strength as a parameter to be considered!

The Examiner then turns to the Maggi reference, which she sees as teaching the use of compression forces of 10 and 30KN respectively, and heating to 30 ºC and 130 ºC with tablets having a melting temperature of about 70 ºC. The Examiner reads Maggi as teaching that an increase in compression will increase crushing strength.

A close look at Maggi, however, will show that of the compression force from 10 KN to 30 KN in the tablet formulated with PEO 900,000 (below Applicants minimum molecular weight range) made some difference in crushing strength (see A1 in Table 2), but when using the higher molecular weight PEO 4,000,000 (which is within Applicants molecular weight range), the increase in crushing strength was negligible and was, in fact, within the error limits of the test (see B1 in Table 2)! This would clearly teach ***away*** from Applicants' claims, which require a molecular weight of component (C) of between 1 and 15 million! For Applicants' molecular weight range of component (C), Maggi would suggest that compression has absolutely no influence on crushing strength.

Further, none of the references cited teach or suggest anything at all about compositions in the form of sintered masses.

It is therefore quite clear that no combination of Oshlack, Zhang and Maggi could ever lead those skilled in the art to Applicants' novel tamper-proof dosage form, and the rejection of claims 1, 2, 4, 6-8, 27-29 and 31 under 35 U.S.C. 103(a) as obvious over Oshlack et al. (US 2003/0064099A) in view of Zhang et al and Maggi et al. should now be withdrawn.

Claims 1, 2, 4, 6-8, 27-29 and 31 stand rejected under 35 U.S.C. 103(a) as obvious over Oshlack et al (US 6,733,783B2), in view of Zhang and Maggi.

The deficiencies of Oshlack et al 2003/0064099A reference in combination with Zhang and Maggi have been discussed above. The substitution of Oshlack US 6,733,783 for the earlier cited Oshlack US 2003/0064099A does not add anything to the combination that would overcome any of the deficiencies discussed above. The present combination of references does not teach or suggest anything at all about a sintered mass dosage form, and does not teach or suggest anything at all about even the possibility of a breaking force of at least 500 N or how such a breaking force may be achieved. The Examiner acknowledges that the primary reference does not teach or suggest the foregoing breaking strength, and relies on the secondary references. Applicants have shown above how the secondary references cannot possibly overcome this

deficiency, and the comments made above in responding to the first art rejection are equally applicable here.

No combination of Oshlack '783, Zhang and Maggi could possibly lead to the product defined by Applicants' claims, and the rejection of claims 1, 2, 4, 6-8, 27-29 and 31 under 35 U.S.C. 103(a) as obvious over Oshlack et al (US 6,733,783B2), in view of Zhang and Maggi should therefore now be withdrawn.

Claims 1, 2, 4, 6-8, 27-29 and 31 stand provisionally rejected for obviousness-type double patenting over claims 1-11, 19, 25-27 and 36 of copending application serial no. 10/567,594. The present claims, as now amended are clearly distinct from those of the '594 application, and cannot in any way reasonably be seen as obvious variants of the copending claims. This provisional obviousness-type double patenting rejection should accordingly be withdrawn.

Claims 1, 2, 4, 6-8, 27-29 and 31 stand provisionally rejected for obviousness-type double patenting over claims 1-11, 19, 25-27 and 30 of copending application serial no. 11/349,537. The present claims, as now amended are clearly distinct from those of the '537 application, and cannot in any way reasonably be seen as obvious variants of the copending claims. This provisional obviousness-type double patenting rejection should accordingly be withdrawn.

Claims 1, 2, 4, 6-8, 27-29 and 31 stand provisionally rejected for obviousness-type double patenting over claims 1-12 and 21of copending application serial no. 10/890,707. The present claims, as now amended are clearly distinct from those of the '707 application, and cannot in any way reasonably be seen as obvious variants of the copending claims. This provisional obviousness-type double patenting rejection should accordingly be withdrawn.

Claims 1, 2, 4, 6-8, 27-29 and 31 stand provisionally rejected for obviousness-type double patenting over claims 1-13 and 22 of copending application serial no. 10/890,763. The present claims, as now amended are clearly distinct from those of the '763 application, and cannot in any way reasonably be seen as obvious variants of the copending claims. This provisional obviousness-type double patenting rejection should accordingly be withdrawn.

Claims 1, 2, 4, 6-8, 27-29 and 31 stand provisionally rejected for obviousness-type double patenting over claims 1-10 and 14-16 of copending application serial no. 11/462,216. The present claims, as now amended are clearly distinct from those of the '216 application, and cannot in any way reasonably be seen as obvious variants of the copending claims. This provisional obviousness-type double patenting rejection should accordingly be

withdrawn.

In view of the present amendments and remarks it is believed that claims 1, 2, 4, 6-8, 27-29 and 31 are now in condition for allowance. Reconsideration of said claims by the Examiner is respectfully requested and the allowance thereof is courteously solicited.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, Applicants request that this be considered a petition therefor. Please charge the required petition fee to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fee or credit any excess to Deposit Account No. 14-1263.

Respectfully submitted,
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